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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,835	09/18/2003	Inge Blomquist	BLOM-105-US	1339

7590 06/14/2005

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EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,835

Applicant(s)

BLOMQUIST, INGE

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: detailed action.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 1 recites the limitation "the longitudinal" and "said space" respectively in lines 9 and 10, page
7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al. US Patent 4,971,054.

4. As to claim 1, Andersson et al. disclose **breathing-speaking valve** (col.2, lines 33-34) **intended to be used as a speaking valve for patients requiring filtration of inspiration air inhaled via tracheostomas and are mounted on a tracheal tube** (col.1, lines 44-46), **which breathing-speaking valve includes housing (1)(fig.1 reference object 16) intended to be attached, via its bottom (2) (fig.1 reference object 6), to the tracheal tube and which comprises a check valve** (col.2 lines 9-11) **in the**

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form of a membrane (fig.1 reference object 8) which check valve opens when the patient inhales and closes when the patient exhales (col.2 lines 52-55) and a filter (7) (fig.1 reference object 4) for filtration of the inspiration air, which filter is located within this membrane (10), characterized in that the filter (10) is laying against a number of ribs (5) (fig.1 reference object 10) located in the bottom (2) of the valve housing (1) and a nipple (13) connection to an oxygen apparatus (col.2, lines 30-32) for oxygen delivery to the inspiration air and mounted substantially perpendicular to the longitudinal direction of the valve housing (1) by the bottom of the valve housing (1), and said nipple (6) opens into the space (14) (fig.1 reference object 15) defined by the ribs (5) and the bottom (2) of the valve housing (1), and also opens into the filter (7) parallel to the extension of the filter (7) (fig.1 seems to depict filter parallel to the ribs), whereby the distribution of the inspiration air and the optional oxygen delivery into the tracheal tube takes place in said space (14) and in the filter (7) (col.2 lines 4-20).

5. Breathing valve according to claim 1, characterized in that an external humidifier is mounted to deliver humidity to the filter (7) (col.4 lines 44-50).

6. Breathing valve according to claim 2, characterized in that the humidifier is connected to the oxygen nipple (6) (fig.1 reference object 13 or 12) or to a special nipple on this oxygen nipple (6).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. US Patent 4,971,054.

8. **As to claims 4, Andersson et al. do not disclose, breathing valve according to claim 1, characterized in that the thickness of the filter (7) is between 0.5 and 3.0 mm, preferably 2 mm, as to claims 5, Andersson et al. do not disclose breathing valve according to claim 1, characterized in that the height of the ribs is between 0.5 and 3.0 mm, preferably 2 mm, as to claims 6, Andersson et al. do not disclose breathing valve according to claim 1, characterized in that the nipple (6) for oxygen delivery has a diameter between 1.5 and 5.5 mm, however, as to claims 4-6, applicant has not establish criticalities associated with the thickness of the filter cited in claim 4, height of the ribs cited in claim 5, and the diameter of the nipple cited in claim 7. Therefore, at the time of the invention it would have been obvious to one of ordinary skills in the art to consider any reasonable dimensions of the structure claimed in claims 4-6 to meet the limitation, and the valve disclosed by Andersson et al. is considered to some dimensions of the filter, rib, and nipple.**

Drawings

9. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "an oxygen apparatus" in claim 1, "an external humidifier" in claim 2, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a

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drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

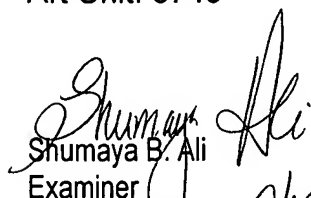

11. The prior art made of record on form PTO-892 and not relied upon shows valve used in combination with a tracheal tube.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.
13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

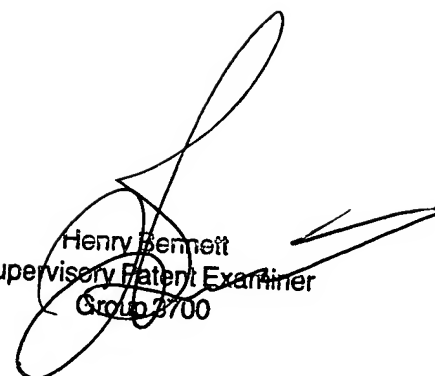
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Shumaya B. Ali
Examiner
Art Unit 3743



Henry Bennett
Supervisory Patent Examiner
Group 3700